UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

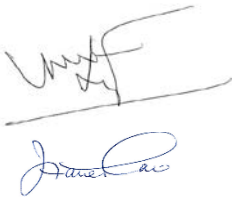
EPA United States Environmental Protection Agency Office of Pesticide Programs

MEMORANDUM

8/17/2017

SUBJECT: **Acute Toxicity Review for MAQUAT 64-NHQ, EPA Reg. No.: 10324-154**

FROM: Narayanan Parthasarathy
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)



THRU: Jenny Tao, Senior Scientist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Eric Miederhoff, PM Team 31 / Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: **Mason Chemical Company**		
Decision No.: **528751**	Submission No.: **1002301**	E-Sub No.: **19000**
DP No.: **440218**	Action Code: **570**	
MRID No(s).: **46426103-46426107 & 50117504**		

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
069149	7173-51-5	Didecyl dimethyl ammonium chloride	2.54%
069105	68424-85-1	Alkyl* dimethyl benzyl ammonium chloride (*50%C_{14}, 40%C_{12},10%C_{16})	1.69%
		Other Ingredients	95.77%
		Total	100.00%

I. BACKGROUND

The **Registrant, Mason Chemical Company**, has submitted an **application for a label amendment** for their **product: *MAQUAT 64-NHQ*, EPA Reg No. 10324-154.** The registrant is proposing to "bridge down" the acute toxicity data of their concentrated product ***Maquat 256-NHQ*, EPA No. 10324-141**, to the **subject product,** except for the **acute inhalation study** for which a **waiver** has been submitted to support the **label amendment.** The subject product is formulated as an end-use and non-integrated antimicrobial pesticide, which is intended for hard, non-porous surfaces in commercial, institutional, and residential settings. The subject product can be applied as a spray.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-35 – Data Matrix (4/17/2017)	☒	☐
Cover letter (4/17/2017)	☒	☐
Transmittal document	☒	☐
Basic CSF, (4/17/2017)	☒	☐
Proposed label, (4/17/2017)	☒	☐
Certification with respect to citation of data EPA Form 8570-34	☒	☐
Acute Oral Toxicity Study (OSCPP 870.1100)	☒	☐
Acute Dermal Toxicity Study (OSCPP 870.1200)	☒	☐
Acute Inhalation Toxicity Study (OSCPP 870.1300)	☒	☐
Primary Eye Irritation Study (OSCPP 870.2400)	☒	☐
Primary Skin Irritation Study (OSCPP 870.2500)	☒	☐
Dermal Sensitization Study (OSCPP 870.2600)	☒	☐
Comments**:**		

III. FINDINGS/RECOMMENDATIONS

1. The **subject product, *Maquat 64-NHQ*, EPA Reg No. 10324-154**, is **a diluted version (1:4)** of the **registrant's own concentrated product *Maquat 256-NHQ*, EPA No. 10324-141 (10.14% DDAC and 6.76% ADBAC).** The **Agency** had **approved** the **Acute Toxicity Profile** for the **concentrated product on 3/31/2005.** It is determined that the acute toxicity data of the concentrated product can be bridged down to support the subject

product for all of the required acute toxicity data except for the acute inhalation endpoint.

2. The registrant is requesting a **waiver** and a **Category IV (MRID # 50117504)** for the **Acute Inhalation Toxicity** for the **subject product**. The rationale is that the subject product was thought to not be able to generate a stable aerosol. The rationale of being unable to generate a stable aerosol was supported with a study, MRID 50017901, that the test substances of 2% and 5% DDAC aqueous solution were not able to generate a stable aerosol for an acute inhalation toxicity study. However, it was determined that this study is unacceptable, because (1) the test substances were 2% and 5% DDAC aqueous solutions and didn't contain the most commonly used inserts; (2) the test substance is deemed not to be substantially similar to the subject product; (3) the study is inadequate and cannot be accepted for addressing the acute inhalation toxicity; and (4) there is potential inhalation risk concern based on the use patterns of the subject product (e.g., used as a spray). The waiver cannot be granted to assign Category IV for acute inhalation toxicity. However, the acute inhalation toxicity study can be waived by assigning **Category II (QUATs content is >2.0%)** based on the Agency "Product Reregistration Batching Guidance for Quaternary Ammonium Compounds (Cases 0350 and 3003)-Acute Mammalian Toxicity Data Requirements" dated Feb 9, 2015.
3. The **Acute Toxicity Profile** for ***Maquat 64-NHQ*, EPA Reg # 10324-154,** is as follows:

Study	Toxicity Category	MRIDs	Study Status
Acute Oral Toxicity	III	46426103	Acceptable
Acute Dermal Toxicity	III	46426104	Acceptable
Acute Inhalation Toxicity	II	Assigned*	
Primary Eye Irritation	I	46426105	Acceptable
Primary Skin Irritation	I	46426106	Acceptable
Dermal Sensitization	Non-sensitizer	46426107	Acceptable

* Product Reregistration Batching Guidance for Quaternary Ammonium Compounds (Cases 0350 and 3003) - Acute Mammalian Toxicity Data Requirements (2/9/2015)

IV. PRODUCT LABELING

1. **The Signal Word: DANGER**
2. The statement, "**Keep Out of Reach of Children** (KORC)", is required. It should appear immediately below the front-panel signal word "**DANGER**".
3. The Agency's Label Review Manual (https://www.epa.gov/pesticide-registration/label-review-manua) indicates the following human-hazard precautionary statement:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

"Corrosive. Causes skin burns and irreversible eye damage. May be fatal if inhaled. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear a NIOSH approved respirator with an organic vapor (OV) cartridge with a combination N, R, or P filter (NIOSH approval number prefix, TC-84A). Wear goggles, face shield or safety glasses. Wear waterproof gloves, long-sleeved shirt, long pants and shoes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse."

4. **FIRST AID:**

   If in Eyes:

   - Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
   - Call a Poison Control Center or doctor for treatment advice.

   If on Skin or Clothing:
   - Take off contaminated clothing.
   - Rinse skin immediately with plenty of water for 15-20 minutes.
   - Call a Poison Control Center or doctor for treatment advice.

   If Inhaled:
   - Move person to fresh air.
   - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
   - Call a Poison Control Center or doctor for treatment advice.

   If Swallowed:
   - Call a Poison Control Center or doctor immediately for treatment advice.
   - Have person sip a glass of water if able to swallow.
   - Do not induce vomiting unless told to do so by a Poison Control Center or doctor.
   - Do not give anything by mouth to an unconscious person.

   "Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage."

   Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact the poison control center at 1-800-222-1222 for emergency medical treatment information.

5. This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye and skin irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). Restricted-Use requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR §152.170 for information on Restricted-Use products.

6. Based upon data placing it in toxicity category I for primary eye and skin irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However,

the Agency does not require products that are assigned Restricted-Use status to be placed in CRP in addition to Restricted-Use Classification. CRP requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions. Thus, CTT recommends that the Product Manager assign this product Restricted-Use classification; if not, the registrant should place this product in CRP.